

MAIL STOP APPEAL BRIEF-PATENTS
PATENT
2503-1193

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Valentino MERCATI

Conf. 7193

Application No. 10/564,100

Group 1791

Filed February 24, 2006

Examiner Michael Felton

PROCESS FOR OBTAINING TOBACCO LEAVES WITH A STANDARDIZED
NICOTINE CONTENT AND/OR IMPROVED COMBUSTIBILITY

APPEAL BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 17, 2010

MAY IT PLEASE YOUR HONORS:

1. REAL PARTY IN INTEREST

The real party in interest in this appeal is:

ABOCA S.P.A. SOCIETA' AGRICOLA, FRAZIONE ABOCA 20,
SANSEPOLCRO (AREZZO), ITALY.

2. Related appeals and interferences

None.

3. Status of claims

Claims 1-23 and 41-46 have been canceled. Claims 24-40 and 47 are pending in the application and stand rejected, from which this appeal is taken.

4. Status of amendments

Per the Advisory Action of October 27, 2010, the Amendment after Final filed on October 19, 2010 has been entered. The entry of this amendment instantly overcame the indefiniteness rejection of the claims upon antecedent basis for "the solvent mixture". The claims at issue are thus those set forth in the Amendment after Final.

5. Summary of claimed subject matter

Independent claim 24: as is set forth in independent claim 24, the present invention pertains to process for treatment of tobacco leaves (*Nicotiana tabacum*) (Page 1, lines 2-4) including the following steps:

- a) drying and curing of the leaves (Page 3, line 18);
 - b) extraction of dried leaves with **a** solvent or mixture of solvents (Page 3, line 19);
 - c) re-drying of the extracted leaves (Page 3, line 20);
- and
- d) elimination of the ribs (Page 3, line 21).

Dependent claim 37: besides the subject matter recited in claim 24, the leaves set forth in the claimed process are re-dried under vacuum (Page 8, lines 8-11).

6. Grounds of rejection to be reviewed on appeal

The first ground for review on appeal is whether claims 24-36 and 47 are sufficiently unpatentable over KIERULFF et al. (US 6,298,859) in view of WOCHNOWSKI et al. (US 3,265,209) to support a rejection under 35 U.S.C. §103(a).

The second ground for review on appeal is whether claims 37-39 are sufficiently unpatentable over KIERULFF et al. in view of WOCHNOWSKI et al. and CLAPP et al. (US 4,941,484) to support a rejection under 35 U.S.C. §103(a).

It is believed that an indefiniteness rejection under 35 USC §112, second paragraph has been overcome by the entry of the after-final Amendment.

7. Argument

7.1 First Ground - KIERULFF et al. in view of WOCHNOWSKI et al.

The present invention pertains to a process for treatment of tobacco leaves (*Nicotiana tabacum*). The process includes the following steps:

- a) drying and curing of the leaves;
- b) extraction of dried leaves with a solvent or mixture of solvents;
- c) re-drying of the extracted leaves; and
- d) elimination of the ribs.

The process of the present invention allows the production of tobacco leaves with a predetermined standardized and desired nicotine content starting from a raw material with a variable nicotine content.

The process according to the present invention is particularly unexpectedly advantageous since it allows the desired nicotine content to be obtained regardless of the initial content, with no need to blend different types of tobacco or to use an expensive processing technique for the elimination of rib

In addition, the final nicotine content can also reach particularly low values, lower than those obtainable by the traditional techniques used to manufacture cigarettes with a low nicotine content.

Furthermore, the process at issue allows to obtain advantageously tobaccos with a reduced chloride content, which otherwise adversely affects the combustibility, texture and flavors of the leaves.

Therefore, this process transforms tobacco leaves with very low or nil combustibility into leaves with ideal combustibility, thus allowing the use of all the leaves of the tobacco plant and or tobacco which would otherwise be unusable because they re not combustible

According to the invention, tobaccos suitable for the production of cigarettes and other smoking products are obtained.

Accordingly, it is evident that the invention yields unexpectedly properties due to the specific process steps and the specific order in which they are carried out.

Thus, the present invention yields unexpected properties no present in the prior art. It is clear the present invention yields more than predictable results and, consequently, the invention is not obvious.

Evidence of these unexpected results can be found in the experiments set forth in the specification. Example 1 of the specification sets forth three procedures according to the invention, which yield the stabilized nicotine content shown in the accompanying Table:

| PROCEDURE | % of nicotine before treatment | % of nicotine after treatment |
|-----------|-----------------------------------|----------------------------------|
| A | 0.96% | 0.23% |
| B | 1.89% | 0.21% |
| C | 2.24% | 0.21% |

Example 2 set forth in the specification showed similar standardization of nicotine content shown in the accompanying table:

| Sample | Nicotine |
|--|----------|
| Tobacco not subjected to the standardization process | 1.271% |
| Tobacco not subjected to the standardization process and formulated with the excipients | 1.183% |
| Tobacco subjected to process standardization process | 0.161% |
| Tobacco subjected to the standardization process and formulated with the excipients | 0.148% |
| Cigarette with tobacco not subjected to the standardization process | 0.92 mg |
| Cigarette with tobacco not subjected to standardization process and formulated with the excipients | 0.81 mg |
| Cigarette with tobacco subjected to the standardization process | 0.135 mg |
| Cigarette with tobacco subjected to the standardization process and formulated with the excipients | 0.125 mg |

Example 4 in the specification showed a reduction in chloride content:

| Cigarette | Tobacco | Result of analytical smoke | % chloride content |
|-----------|---|----------------------------|--------------------|
| A | Virginia Bright Batch 2B012 | Negative | 1.2 |
| B | Virginia Bright Batch 2B012 Subjected to the process described below | Positive | 0.6 |

In KIERULFF et al. a step which involves the use of an enzyme is foreseen, in particular the tobacco extract is contacted with a **phenol oxidizing enzyme** to produce one or more oxidized phenolic compounds.

The use of any kind of enzyme is not foreseen in the present invention.

WOCHNOWSKI et al. only disclose a process and an apparatus for carrying out the elimination of ribs. No mention is made in WOCHNOWSKI et al. about the previous steps of:

- a) drying and curing of the leaves;
- b) extraction of the dried leaves with a solvent or mixtures of solvents; and
- c) redrying of the extracted leaves

Accordingly, neither KIERULFF et al. nor WOCHNOWSKI et al. disclose or infer the first step of drying and curing the leaves before the extraction step is carried out. Indeed, there is no teaching in KIERULFF et al. or in WOCHNOWSKI et al. that the extraction is to be performed on previously dried and cured leaves.

Therefore one of ordinary skill and creativity in the art would not produce a claimed embodiment of the present invention from a knowledge of KIERULFF et al. and WOCHNOWSKI et al. and a *prima facie* case of unpatentability has not been made.

Moreover, even if one assumes *arguendo* that some *prima facie* unpatentability could be alleged, this unpatentability would be fully rebutted by the unexpected results discussed above.

Additionally, the unexpected results do not offer mere rebuttal, but must be considered in light of the deficiencies of the *prima facie* case.

Both the inability to establish *prima facie* obviousness and the unexpected results should be viewed synergistically as establishing patentability of the claimed invention. "The determination of obviousness, vel non, requires that all the evidence be considered together . . . if rebuttal evidence of adequate weight is produced, a holding of *prima facie* obviousness, being but a legal inference from previously uncontradicted evidence, is dissipated. The objective evidence of unobviousness is not evaluated for its 'separate knockdown ability' against the 'stonewall' of the *prima facie* case . . . but is considered together with all other evidence, in determining whether the invention is as a whole would have been obvious to a person of ordinary

skill in the field of the invention." (citations omitted).
Applied Materials Inc. v. Advanced Semiconductor Materials, 98
F.3d 1563, 1574, 40 USPQ2d 1481, 1486 (Fed. Cir. 1996).

This rejection over KIERULFF et al. in view of
WOCHNOWSKI et al. should accordingly be withdrawn.

7.2 Second Ground - KIERULFF et al. in view of WOCHNOWSKI et
al. and CLAPP et al.

The deficiencies of KIERULFF et al. and WOCHNOWSKI
et al. have been discussed above.

In CLAPP et al. one step of drying after an
extraction process is described, which however, as also
admitted the Official Action of September 25, 2009, is not
exactly that intended by the present invention. Taking into
account the above-mentioned considerations pointed out for
claims 24-34 and in view of the fact that dependent claims 37-
39 incorporate all the technical features of the independent
claim 24 (on which they depend), the Appellant believes that
in view of non-obviousness of the general process cover by
independent claim 24, also dependent claims thereof should be
considered as inventive.

This rejection over KIERULFF et al. in view of
WOCHNOWSKI et al. and CLAPP et al. should accordingly be
withdrawn.

8. Conclusion

The Appellant has demonstrated that the Examiner has failed to successfully allege that the rejected claims are *prima facie* unpatentable. It is clear that the inventive process for treating tobacco leaves has advantages unseen over the applied art. For the reasons advanced above, it is respectfully submitted that all the rejected claims in this application are allowable. Thus, favorable reconsideration and reversal of the rejection under 35 USC §103, by the Honorable Board of Patent Appeals and Interferences, are respectfully solicited.

Please charge the requisite Appeal Brief fee in the amount of \$270 to our credit card.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,
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9. Claims Appendix

24. A process for treatment of tobacco leaves (*Nicotiana tabacum*) comprising the following steps:

- a) drying and curing of the leaves;
- b) extraction of dried leaves with a solvent or mixture of solvents;
- c) re-drying of the extracted leaves; and
- d) elimination of the ribs.

25. The process as claimed in claim 24, wherein the solvent is selected from methanol, ethanol, propanol, isopropanol, acetone, ethylene glycol, water or mixtures thereof.

26. The process as claimed in claim 25, wherein the solvent is ethanol.

27. The process as claimed in claim 25, wherein the solvent is an ethanol/water mixture with a strength of between 20° and 80°.

28. The process as claimed in claim 27, wherein the mixture has a strength of 50°.

29. The process as claimed in claim 24, wherein a weight ratio between tobacco and solvent mixture is between 1: 5 and 1: 30.

30. The process as claimed in claim 29, wherein the weight ratio between tobacco and solvent mixture is 1 : 16.

31. The process as claimed in claim 24, wherein the extraction carried out for a time of between 3 and 16 hours.

32. The process as claimed in claim 31, wherein the extraction carried out for 8 hours.

33. The process as claimed in claim 24, wherein an extraction temperature is between 20 and 80°C.

34. The process as claimed in claim 33, wherein the extraction temperature is 60°C.

35. The process as claimed in claim 24, wherein the extraction is performed 1-5 times.

36. The process as claimed in claim 35, wherein the extraction carried out once.

37. The process as claimed in claim 24, wherein the leaves are re-dried under vacuum.

38. The process as claimed in claim 24, wherein the leaves are re-dried for 36-48 hours.

39. The process as claimed in claim 24, wherein the leaves are re-dried at the temperature of 35°C.

40. The process as claimed in claim 24, wherein Virginia Bright tobacco leaves are used.

47. The process as claimed in claim 25, further comprising adjusting a pH of the solvent with buffers.

10. Evidence Appendix

None.

11. Related Proceedings Appendix

None.